



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,379	07/21/2006	Kevin Stamp	7095MH-5	1087

22442 7590 07/31/2008
SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER

MEDWAY, SCOTT J

ART UNIT	PAPER NUMBER
----------	--------------

4116

MAIL DATE	DELIVERY MODE
-----------	---------------

07/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,379	Applicant(s) STAMP, KEVIN	
	Examiner SCOTT MEDWAY	Art Unit 4116	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :07/21/2006, 02/09/2007, 10/09/2007, 02/05/2008, 03/27/2008.

DETAILED ACTION

1. In response to the Preliminary Amendment filed 07/21/2006, claim 32 has been canceled, and claims 1-31 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 23, 24 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 23 and 24, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). For the purposes of examination, "or the like" will be interpreted as any material having protective properties.

Regarding claim 31, the phrase "a spring housing intermediate the outer housing and the spring housing" is indefinite because the spring housing may not be intermediate to itself. For the purposes of examination and in light of previously-recited claims, the aforementioned phrase will be interpreted as "a spring housing intermediate the outer housing and *the inner housing*."

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-23, 25, and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergens et al (U.S. Pat. No. 6,270,479 B1).

Regarding claims 1, 29 and 30, Fig. 1 of Bergens et al discloses an injection device comprising a barrel (121); a needle (123) at one end of the barrel, the needle being moveable in and out of the outer housing (e.g. 110, 112) of the barrel as shown in Figs. 1A and 1B; a plunger mechanism (e.g. 125, 126) with a portion (125) being moveable within the barrel; an inner housing; and an energy source (141) in communication with the inner housing. The device has three positions, namely a first position (Fig. 1B) in which an inner housing (e.g. 130) has at least one radially flexible tags 132, 133 (see Fig. 1A) in communication with the barrel such that in use, the plunger and barrel are moveable axially to move the needle out of the outer housing; a second position (Figs. 1C and 1D) in which an inner housing in which a radially flexible tag (143) is in communication with the plunger but not the barrel such that the plunger is moveable to expel medicament through the needle as shown; and a third position (Fig. 1A) in which radially flexible tags (132, 133, 143) are neither in communication with the plunger nor the barrel such that in use, the barrel, plunger and needle are retracted into the outer housing.

Regarding claim 2 and 31, Fig. 1A of Bergens et al shows a spring housing (155) intermediate to the inner housing (as described) and the outer housing (110).

Regarding claim 3, the aforementioned tags are shown to have portions situated at angles to flexible legs.

Regarding claims 4 and 5, Fig. 1A and 1C of Bergens et al shows tags (143) being situated at the rear end of the housing and moveable radially into and out of communication with the plunger as described.

Regarding claims 6 and 11, Fig. 1A of Bergens et al shows rear tag (143) in a relaxed position (as per claim 6) and forward tags (132, 133) in a relaxed position (as per claim 11) prior to being compressed into a non-relaxed position before initiating an injection (Figs. 1B and 1C).

Regarding claim 7, Fig. 1A of Bergens et al shows a tag (143) being out of communication with the plunger and situated in alignment with the spring housing (155).

Regarding claim 8, Bergens et al discloses an alternative embodiment in Fig. 3A having a rear tags (353) primarily T-shaped.

Regarding claims 9 and 10, Fig. 1A of Bergens et al shows tags (132, 133) situated at the forward end of the inner housing (130) and moveable radially into and out of communication with the barrel (see Figs. 1A and 1B).

Regarding claim 12, Fig. 1A of Bergens et al shows the forward tags being out of communication with the barrel when aligned with a corresponding recess portion of the outer housing 113 (the recess being formed by the coming together of portion 113 and a section of the inner housing 133 and more clearly shown in Fig. 1B).

Regarding claim 13, the aforementioned forward tags are shown to be L-shaped in Fig. 1 of Bergens et al.

Art Unit: 4116

Regarding claims 14 and 15, Bergens et al discloses the energy source comprising compressed gas (col. 8, line 46) (as per claim 14) or a spring (col. 8, line 48).

Regarding claims 16 and 17, Bergens et al discloses a ratchet-teeth-like mechanism for allowing the inner housing to move axially forward with respect to the outer housing (col. 15, lines 48-58)

Regarding claim 18, Fig. 3C of Bergens et al shows a guide means (353) having a protrusion as shown on a spring housing (351) and cooperating with a corresponding recess on an interior surface of the outer housing (313) to guide the axial movement of the spring and outer housings.

Regarding claim 19, Fig. 1A of Bergens et al shows the needle biased to be normally wholly the housing by means of a spring intermediate the barrel and outer housing.

Regarding claims 20 and 21, Figs. 3H and 3J of Bergens et al show an alternative embodiment wherein the syringe is removable from the device, the syringe containing the needle (as per claim 20) and the barrel and plunger (as per claim 21).

Regarding claim 22 and 23, Fig. 3B of Bergens et al shows a removable needle sheath (327) which protects the needle (as per claim 22) and a button means (335) for removing the protective sheath from the device (as per claim 23).

Regarding claim 25, Bergens discloses a injection lock, acting as a safety lock substantially preventing relative forward movement of said outer housing (col. 7, lines 30-34).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bergens et al (U.S. Pat. No. 6,270,479 B1) in view of Selenke (U.S. Pat. No. 4,958,622).

Regarding claim 24, it is noted that the needle cover of Bergens et al does not include pulling means including a floating rivet intermediate the needle cover and protective sheath whereby twisting forces applied to the needle cover are prevented from being transmitted to the sheath. Fig. 1 of Selenke discloses an injection device with a needle cover (34) and sheath (33) including a floating rivet portion (39) whereby twisting forces acting on the cover are not

Art Unit: 4116

transferred to the sheath. It would have been obvious to one of ordinary skill in the art at the time of the invention to merely combine the needle cover and sheath of Selenke to the injection device of Bergens, maintaining the operability of the injection device as disclosed by Bergens while improving the sterility of the device by outfitting the device with a needle cover and sheath where the cover is operable to be twisted and removed without removing the sheath.

8. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergens et al (U.S. Pat. No. 6,270,479 B1) in view of Haber et al (U.S. Pat. No. 5,634,906).

Regarding claims 26-27, it is noted that the injection device as described by Bergens et al does not comprise a viewing window in the barrel and a viewing window within the outer housing. Haber et al disclose a shield for a dose metering syringe, comprising in Fig. 5 a window (72) located on an outer housing (68) and an inner window (30) located on a barrel 28 (as per claim 26) where medicament is viewed through the two windows, and further, as shown in Fig. 6 of Haber, the two portions are slideable past one another so that the inner housing moves intermediate the viewing window. It would have been obvious to one of ordinary skill in the art at the time of the invention to merely add the windows of Haber et al to the outer housing and barrel of Bergens et al in order to improve the visibility of medicament within the barrel and to ensure synchronous movement between the outer housing and the barrel during proper use of the device.

9. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bergens et al (U.S. Pat. No. 6,270,479 B1) in view of Bechtold et al (U.S. Pat. No. 5,042,977).

Art Unit: 4116

Regarding claim 28, it is noted that the device of Bergens et al does not comprise means for emitting an audible indication to a user that the injection is complete. Bechtold et al discloses an injection device having audible clicking means produced during medication injection (col. 10, lines 12-18), interpreted as including a final click for indicating when injection is complete (as the actuating knob as disclosed is moved to its distal end). It would have been obvious to one of ordinary skill in the art at the time of the invention to outfit the device of Bergens et al with the audible clicking means of Bechtold et al, e.g. combining the audible clicking means to one of the spring mechanisms of Bergens et al, in order to improve the level of dosage achieved and to ensure a patient is aware when a dosage cycle has completed.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Nieto et al (U.S. Pat. No. 4,976,724) discloses an ejector mechanism having spring mechanisms and tags.

Tibbs (U.S. Pat. No. 3,702,608) discloses a painless injection device with a powered plunger.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCOTT MEDWAY whose telephone number is (571)270-3656. The examiner can normally be reached on Monday through Friday, 7:30 A.M. to 5:00 P.M. EST.

Art Unit: 4116

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Cheng can be reached on (703)272-7733. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott J. Medway/
07/23/08

/Joe H Cheng/
Supervisory Patent Examiner
Art Unit 4116